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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/854,568 | 05/15/2001 | Samuel Bogoch | 9425/46702 | 8438 |

7590 09/20/2004

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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------------|----------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/854,568 | BOGOCH, SAMUEL | |
| | Examiner | Art Unit | |
| | David A Saunders, PhD | 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Claims 1-13 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a process for immunizing against malignin, classified in class 424, subclass 277.1.
- II. Claims 6 and 13, drawn to anti-malignin antibodies and conjugates thereof, classified in class 530, subclass 387.7 and 391.7.
- III. Claims 7-11, drawn to a device comprising cells having immunological specificity for malignin, classified in class 435, subclass 395+ and class 604 subclass 5.01.
- IV. Claim 12, drawn to a process for detecting anti-malignin antibodies or immune cells, classified in class 435, subclass 7.23+.

The inventions are distinct, each from the other because:

Inventions I and II are related as a process of making and a product made.

The inventions are distinct if either or both of the following can be shown : (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process.

In the instant case, the product of Group II could have been obtained by methods other than that recited in the method of Group I . In the era of producing monoclonal antibodies, the antibody as a composition can be obtained before one has characterized the cognate antigen (s).

Note, it is not even clear that the antibody product of Group II is the product of the process of Group I . Invention II could also be considered unrelated to the

process of Group I, since that process does not require the isolation of the antibody, that process could be merely an immunization against cancer, in which no antibody is isolated from the subject.

The processes of Groups I and III are unrelated, in that they use different agents (a malignin antigen preparation and a device bearing immune cells, respectively) and in that these methods can be practiced separately—e.g. on different patients and/or at different times upon the same patient.

The antibody of Group II would not be used in the device of Group III, since the latter has immune cells, rather than antibody.

The immunization process of Group I and the detecting process of Group IV are not related in that a clinician typically diagnoses the cancerous state of a subject (e.g. as in Group IV) prior to any treatment process of the cancer (e.g. as in Group I). Also numerous other treatments of cancer, other than that of Group I, could be employed—e.g. radiation.

The antibody of Group II would not be used in the process of Group IV. For practice of the latter, one would provide the malignin antigen, not the antibody, as a reagent to bind the antibodies being detected.

The cellular device of Group III and the detecting process of Group IV are unrelated in that a clinician would diagnose the cancerous state of a subject prior to any treatment of the cancer with the device of Group III. Also numerous other treatments of cancer, other than those using the device of Group III, could be practiced.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00a.m to 5:30p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit: 1644

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Saunders/tgd

September 15, 2004

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182/687